

In the Claims:

Please add the following claims 7 to 31 and cancel claims 1 to 6 without prejudice:

7. A method of controlling testosterone blood level in a person for therapeutic purposes, said method comprising administering an effective amount of a mixture of testosterone and at least one testosterone ester to said person in a predetermined ratio of said testosterone to said at least one testosterone ester of 1:100 to 1:1;

wherein said at least one testosterone ester comprises a carboxylic acid radical having from one to twenty carbon atoms; and

wherein said effective amount and said at least one testosterone ester are selected so that a predetermined testosterone profile is provided by said administering to said person.

A 6
8. The method as defined in claim 7, wherein said carboxylic acid radical has a chain length and steric structure selected according to said predetermined testosterone profile.

9. The method as defined in claim 7, wherein said least one testosterone ester is selected from the group consisting of testosterone acetate, testosterone propionate, testosterone enantate, testosterone cipionate, testosterone cyclohexanecarboxylate, testosterone undecanoate and testosterone bucyclate,

so that said testosterone blood level varies according to an endogenous circadian body rhythm.

10. The method as defined in claim 7, wherein said at least one testosterone ester includes testosterone undecanoate in order to provide an extended time-release half life.

11. The method as defined in claim 7, wherein said person is an elderly man suffering from partial androgen deficiency, whereby said partial androgen deficiency is corrected.

A4

12. The method as defined in claim 7, wherein said administering comprises buccal application of a bioadhesive tablet containing said mixture of said testosterone and said at least one testosterone ester.

13. The method as defined in claim 12, wherein said bioadhesive tablet is two-layered and made by a method comprising the steps of:

a) embedding said testosterone and said at least one testosterone ester, separately or together, in an organic polymer, optionally together with at least one auxiliary ingredient, by a spray-drying process, so as to form an active ingredient premix with a ratio of said testosterone to said at least one testosterone ester of from 1:100 to 1:1; and

b) forming said bioadhesive tablet with an active ingredient layer and an

adhesive layer, wherein said active ingredient layer comprises an effective amount of said active ingredient premix, and wherein said adhesive layer is a mixture of other auxiliary ingredients, said other auxiliary ingredients including a bioadhesive polymer, so that said bioadhesive tablet includes means for said buccal application.

A6
14. The method as defined in claim 13, wherein said ratio is 1:10 to 1:1.5 and said active ingredient premix is made by spray-drying a solution of said organic polymer, said testosterone, said at least one testosterone ester and said at least one auxiliary ingredient in a solvent.

15. The method as defined in claim 13, further comprising mixing said active ingredient premix with at least one of a filler and a lubricant, mixing said bioadhesive polymer with said at least one of said filler and said lubricant and compressing mixtures resulting from said mixing to form said bioadhesive tablet with said active ingredient layer and said adhesive layer.

16. A method of manufacturing a bioadhesive tablet for controlling testosterone blood level in a person for therapeutic purposes, said method comprising the steps of:

a) embedding testosterone and at least one testosterone ester, separately or together, in an organic polymer, optionally together with at least one auxiliary ingredient, by a spray-drying process, so as to form an active ingredient premix

with a ratio of said testosterone to said at least one testosterone ester of from 1:100 to 1:1; and

b) forming said bioadhesive tablet with an active ingredient layer and an adhesive layer, wherein said active ingredient layer comprises an effective amount of said active ingredient premix, and wherein said adhesive layer is a mixture of other auxiliary ingredients, said other auxiliary ingredients including a bioadhesive polymer, so that said bioadhesive tablet includes means for buccal administration.

14

17. The method as defined in claim 16, wherein said at least one testosterone ester has an ester group, said at least one testosterone ester is selected according to chain length and steric structure of said ester group, and wherein a dosage of said testosterone and said at least one testosterone ester in said bioadhesive tablet is selected, so that a predetermined testosterone profile is provided when said bioadhesive tablet is administered to said person.

18. The method as defined in claim 16, wherein said least one testosterone ester is selected from the group consisting of testosterone acetate, testosterone propionate, testosterone enantate, testosterone cipionate, testosterone cyclohexanecarboxylate, testosterone undecanoate and testosterone bucyclate, so that said testosterone blood level varies according to an endogenous circadian body rhythm when said bioadhesive tablet is administered to said person.

19. The method as defined in claim 16, wherein said at least one testosterone ester includes testosterone undecanoate in order to provide an extended time-release half-life.

20. The method as defined in claim 16, wherein said ratio is 1:10 to 1:1.5 and said active ingredient premix is made by spray-drying a solution of said organic polymer, said testosterone, said at least one testosterone ester and said at least one auxiliary ingredient in a solvent.

21. The method as defined in claim 20, wherein said solvent is ethanol.

22. The method as defined in claim 20, wherein said organic polymer is polyvinyl pyrrolidone or hydroxypropyl-methylcellulose.

23. The method as defined in claim 20, wherein said bioadhesive polymer is a polyacrylate polymer.

24. The method as defined in claim 20, wherein said at least one auxiliary ingredient is selected from the group consisting of binders, fillers, lubricants, surfactants and a disintegration accelerator.

25. The method as defined in claim 20, further comprising mixing said active ingredient premix with at least one of a filler and a lubricant, mixing said

bioadhesive polymer with said at least one of said filler and said lubricant and comprising resulting mixtures therefrom to form said bioadhesive tablet with said active ingredient layer and said adhesive layer.

26. A two-layer bioadhesive tablet for controlling testosterone blood level in a person for therapeutic purposes, said two-layer bioadhesive tablet having an active ingredient layer and an adhesive layer, wherein said two-layer bioadhesive tablet is made by a method comprising the steps of:

A 4
a) embedding said testosterone and at least one testosterone ester, separately or together, in an organic polymer, optionally together with at least one auxiliary ingredient, by a spray-drying process, so as to form an active ingredient premix with a ratio of said testosterone to said at least one testosterone ester of from 1:100 to 1:1; and

b) forming said bioadhesive tablet with the active ingredient layer and the adhesive layer, wherein said active ingredient layer comprises an effective amount of said active ingredient premix, and wherein said adhesive layer is a mixture of other auxiliary ingredients, said other auxiliary ingredients including a bioadhesive polymer, so that said bioadhesive tablet includes means for buccal administration.

27. The two-layer bioadhesive tablet as defined in claim 26, wherein said ratio is 1:10 to 1:1.5 and said active ingredient premix is made by spray-drying a solution of said organic polymer, said testosterone, said at least one testosterone ester

and said at least one auxiliary ingredient in a solvent.

28. The two-layer bioadhesive tablet as defined in claim 27, wherein said solvent is ethanol.

29. The two-layer bioadhesive tablet as defined in claim 26, wherein said at least one auxiliary ingredient is selected from the group consisting of binders, fillers, lubricants, surfactants and a disintegration accelerator.

A4
30. The two-layer bioadhesive tablet as defined in claim 26, further comprising mixing said active ingredient premix with at least one of a filler and a lubricant, mixing said bioadhesive polymer with said at least one of said filler and said lubricant and compressing resulting mixtures from said mixing to form said bioadhesive tablet in said active ingredient layer and said adhesive layer.

31. The two-layer bioadhesive tablet as defined in claim 26, wherein said least one testosterone ester is selected from the group consisting of testosterone acetate, testosterone propionate, testosterone enantate, testosterone cipionate, testosterone cyclohexanecarboxylate, testosterone undecanoate and testosterone bucyclate, so that said testosterone blood level varies according to an endogenous circadian body rhythm when said bioadhesive tablet is administered to said person.